

Expert Commentary Series

Debunking Antivaccinationist John Stone and the CDC “Whistleblower”: A Review of John Stone’s “DeStefano Rides Again: GSK Rotavirus Vaccine Study Loses 80% Of Cases And 18 Deaths”

(*Age of Autism*, August 25, 2015, reposted October 27, 2015)

**by Joel A. Harrison, PhD, MPH
December 5, 2015**

Introduction

A number of organizations as well as bloggers have arisen over the past several decades claiming that vaccines and/or their ingredients cause a number of disorders. The results of their efforts have been a decline in vaccine coverage and a rise in previously rare childhood diseases, resulting in unnecessary suffering, hospitalizations, long term disabilities, and even deaths.

I’ve written several articles for *Every Child By Two*. Each of them shows clearly the poor scholarship, deficient science, and often lack of common sense contained in articles written by antivaccinationists. The bottom line is they don’t know what they are talking about. If people are to decide on whether to vaccinate their children or not, it should be based on scholarly, well-grounded science, and reflect basic common sense, not claims made by people who are deficient in these.

John Stone is the UK editor for the online blog, *Age of Autism*. In a recent article, Stone writes (Stone, 2015a):

Frank DeStefano, the CDC's Director of Immunization Safety and the lead author at the centre of CDC whistleblower William Thompson's allegations about destroying MMR/autism data, is involved in another case of apparently hiding data, this time involving intussusception and death, in a newly published paper concerning the safety of GSK's rotavirus vaccine, Rotarix.

Last month Representative Posey revealed Congress that Thompson told Dr Brian Hooker in a taped telephone conversation regarding the DeStefano MMR paper that:

Sometime soon after the meeting, we decided to exclude reporting any race effects, the co-authors scheduled a meeting to destroy documents related to the study. The remaining four coauthors all met and brought a big garbage can into the meeting

room and reviewed and went through all the hard copy documents that we had thought we should discard and put them in a huge garbage can.

The new CDC based study of GSK's Rotarix vaccine by Haber et al, of which DeStefano is senior author and therefore responsible for research integrity, admits a small association with the serious condition of intussusception (an intestinal obstruction secondary to the inversion of one portion of the intestine within another). The paper states that from February 2008 to December 2014 the Vaccine Adverse Event Reporting System (VAERS) "received 108 confirmed insusceptible reports after RV1" (Rotarix). However, a careful review of the database reveals no less than 565 cases for the period. The paper claims to have excluded only 4 reports as unconfirmed (making a total of only 112). (Stone, 2015a; reposted 2015b)

In an Addendum posted a day after the reposting of his article, Stone writes:

I took this article down for 24 hours to consider the points made by "n davis" and "n davis is correct". I had overlooked the fact that the paper selects US cases only - that there are only a trickle of cases from the US against a relative flood from abroad - and this is basis of massive selection bias, particularly in relation to deaths. It also shows that the US reporting system while always vastly inadequate is wilting. Pharmaceutical companies are required by law to forward reports from abroad where they come to their attention: there is nothing in n davis's claim that these reports were unavailable to DeStefano - anyone interested in the safety of the vaccine to US children or any other would have considered all of the reports. (Stone 2015c)

Vaccine Adverse Events Reporting System (VAERS)

As Stone did, I went to the NVIC webpage "Search the VAERS database" (Available at: <http://www.medicare.gov/vaersdb/index.php>), filled in the appropriate information, e.g., date range and United States, and got the exact same numbers that the Haber *et al.* (2015) article presented. It was quite simple, only taking a few minutes (see below). Note that I did this after reading Stone's original posting of his article.






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Found 109 cases where Location is U.S. States and Vaccine is RV1 and Symptom is Intussusception or Small intestinal intussusception reduction and Onset Date from '2008-01-01' to '2014-12-31'

Table

 Age	 Count	 Percent
< 3 Years	108	99.08%
Unknown	1	0.92%
TOTAL	109	100%

Case Details

So Stone writes: “However, a careful review of the database reveals no less than 565 cases for the period.” And then: “I had overlooked the fact that the paper selects US cases only.” I guess he wasn’t all that careful, missing that the Haber *et al.* article clearly stated:

1. “We reviewed all US reports of intussusception after rotavirus vaccination with RV1 in VAERS from the date of FDA approval on February 1, 2008 through December 31, 2014.” (Haber, 2015, p.2874)
2. “Fig. 1. Number of reports to VAERS of intussusception cases after all doses of Rotarix vaccine (RV1), by onset interval in days (United States, from April 2008 to December 2014).” (Ibid, p.2875)
3. Or the final paragraph of the article: “In summary, after distribution of 10.9 million doses of RV1 in the United States, we observed an excess risk of 1.6 cases of intussusception per 100,000 vaccinations during 3–6 days after the first dose. This level of increased risk in the United States would translate theoretically to 68 (95% CI = 13, 247) excess annual intussusception events following dose 1 of RV1, based on a U.S. birth cohort of 4.26 million [31] under a hypothetical scenario of 100% vaccination coverage.” (ibid, p.4876)

Even when “admitting” he was wrong in his Addendum, Stone makes a lame attempt to justify his attacks on DeStefano’s integrity: “I had overlooked the fact that the paper selects US cases only - that there are only a trickle of cases from the US against a relative flood from abroad - and this is basis of massive selection bias, particularly in relation to deaths. It also shows that the US reporting system while always vastly inadequate is wilting. Pharmaceutical companies are required by law to forward reports from abroad where they come to their attention.” Yes, “pharmaceutical companies are required by law to forward reports from abroad where they come to their attention.” However, they are actually

required by law to forward ALL reports, not just foreign ones: “The National Childhood Vaccine Injury Act (NCVIA) of 1986 requires health professionals and vaccine manufacturers to report to the U.S. Department of Health and Human Services (HHS) specific adverse events that occur after the administration of routinely recommended vaccines. In response to NCVIA, CDC and FDA established VAERS in 1990.” (VAERS, 2015)

In regards to VAERS, “Anyone can report any vaccine AE [Adverse Event] to VAERS. . . healthcare providers are mandated by law to report certain AE after vaccination, and they are encouraged to report any clinically significant event occurring after vaccination, even if they are not certain the event is causally related to a vaccine(s).” (CDC, 2014)

It is absurd to assume pharmaceutical companies would obey the law in reporting foreign adverse events; but not those in the US or that there would be proportionately more reporting of adverse events from foreign sources to pharmaceutical companies than American. Stone doesn’t even try to give any evidence of this. We should just accept his fantasy world.

The Haber *et al.* (2015) article also stated: “For all intussusception reports we obtained information on clinical features, treatment, hospital course, and vaccination history, including vaccine type, dose number, and date of vaccination, along with copies of vaccination records. In this analysis, intussusception events were considered confirmed if they met the Level 1 criteria of the Brighton Collaboration case definition.”

Standards of care and diagnoses differ from country to country. There are just too many factors that could affect the validity of foreign reports, including the source since anyone can submit a report to VAERS. Deaths relate to type/quality of care, diagnoses may be different. In addition, it would have been difficult to near impossible to obtain the above information for foreign reports.

I think most Americans would be interested in risks found in this country. As an analogy, imagine the US Department of Justice crime statistics showing a decrease of murders in the US; but someone challenges them by listing ALL Americans who died violently, including tourists abroad, those living abroad, and even those who joined terrorist groups such as ISIS. How would that give an accurate statistic of safety in the US?

Haber’s limiting of data to the US is completely justified on both those grounds: the difficulty, or even impossibility, of verifying the information for cases from abroad and the relevance of United States data to understand the risk to children in the United States.

As Stone wrote: “I had overlooked the fact that the paper selects US cases only - that there are only a trickle of cases from the US against a relative flood from abroad - and this is basis of massive selection bias, particularly in relation to deaths.”

Since we don’t even know the denominator, that is, the population represented by the non-US reports, it is impossible to judge the relative number of reports. Perhaps Stone is unaware that the US population is about 300 million compared with over 6 billion in the rest of the world? In other words, it’s completely unclear that the cases from abroad, coming out of a much larger population, are, in fact, a “flood”. So, once again Stone doesn’t know what he is talking about or disregards the facts.

Indefensible/Dishonest Data Inclusions and Exclusions

For the moment, let us assume that in evaluating vaccines we should consider worldwide data as Stone suggests. Then why do antivaccinationists downplay the risks from measles using only data from the US? Is Stone now willing to include the measles deaths from abroad? According to the World Health Organization (WHO): “In 2013, there were 145 700 measles deaths globally.” (WHO, 2015) Or, perhaps Stone is willing to include the deaths from rotavirus worldwide, in 2008 estimated at 453,000, when critiquing the rotavirus vaccine? So, if we were to include the 18 non-US deaths from VAERS, then how would we evaluate a vaccine when there is a risk of 18 deaths from the vaccine but the vaccine would prevent a large portion of 453,000 deaths? And this is assuming that some of the cases of intussusception would not have resulted from the natural virus or other causes had the infants not been vaccinated.

It is indefensible and dishonest to include world level data when they suit one’s interest and to exclude similar data when they don’t. However, just to make sure that people reading this article understand, even without the worldwide data, both measles and rotavirus would still pose serious risks to Americans if allowed to reemerge. For instance, “In the United States in the prevaccine era, approximately 500,000 cases of measles were reported each year, but, in reality, an entire birth cohort of approximately 4 million persons was infected annually. Associated with these cases were an estimated 500 deaths, 150,000 cases with respiratory complications, 100,000 cases of otitis media, 48,000 hospitalizations, 7,000 seizure episodes, and 4,000 cases of encephalitis, which left up to one quarter of patients permanently brain damaged or deaf.” (Strebel, 2013, p. 358) For rotavirus, “prior to the use of rotavirus vaccines . . . by the end of the second or third year of life, 60% to 80% of all children developed a rotaviral diarrheal illness (approximately 2.7 million episodes per year), 1 in 6.5 sought medical attention, 1 in 70 (55,000 to 70,000 patients) were hospitalized, and 1 in 66,000 to 1 in 200,000 (20 to 60 children) died as a result of rotavirus.” (Clark, 2013, p.674) For a more extensive discussion of measles, see the section on page 9 “Measles Without Vaccinations” in one of my previous ECBT articles, “Wrong About Measles, Cancer & Autism: A Review of Dan Olmsted’s Article ‘Weekly Wrap: Measles, Cancer, Autoimmunity, Autism’ (*Age of Autism*, May 17, 2014)” (May 28, 2015, Available at: http://www.ecbt.org/images/articles/Wrong_About_Measles_Cancer_Autism.pdf)

The US population has doubled since the 1950s, measles is just as contagious (but a plane flight away) and there is still no scientifically validated treatment. Prior to the advent of antibiotics measles had extremely high rates of mortality, mostly due to secondary opportunistic bacterial infections (see my previous ECBT article referred to above); however, there has been a rise in antibiotic resistance, and without a vaccine, one could easily estimate a doubling or more of the harms described above. In addition, nowadays with an increase in single-parent families and in families where both parents work, even families facing non-hospitalized cases of measles and rotavirus would often, besides seeing their child suffer, suffer substantial financial loss. And, if one were to add up the lost school days from all the vaccine-preventable diseases, they would also be substantial. For those interested, a recent article looked at the economic costs, including “opportunity costs associated with parents who miss work to care for their sick children or cohort members themselves who miss work owing to vaccine-preventable illness.” (Zhou, 2014)

Vaccines have been shown to reduce illness, disabilities, and deaths, and, thanks to vaccines, rates of childhood deaths have plummeted, resulting in a significant increase in average life expectancy. For instance, Riley writes: “Between 1800 and 2000 life expectancy at birth rose from about thirty years to a global average of sixty-seven years, and to more than seventy-five years in favored countries” (Riley, 2001, back cover) and “Within this building of health the most valuable elements of the health transition [increase in life expectancy] fall into two categories. The first consists of contributions from technicians and experts, and is led by immunization and antibiotics.” (ibid, 2001, p.222; for specifics on vaccine effects on morbidity and mortality, see: Armstrong, 1999; CDC, 2015ab; Cunningham, 2010; Roush, 2007; van Panhuis, 2013; Whitney, 2014)

VAERS Is Not the Only Vaccine Surveillance System

My papers for ECBT tend to be quite long, including extensive reference lists (with hyperlinks when available) as I want to make as irrefutable a case as possible, at least, as irrefutable as one mere mortal can, so, I will just briefly mention that VAERS is not the only source for finding possible associations between vaccines and adverse events (e.g. CDC, 2015c; CDC, 2015d; LaRussa, 2011; Offit, 2013). For instance, the FDA established the Post-Licensure Rapid Immunization Monitoring Program (PRISM) as part of the Mini-Sentinel System in 2008. (Baker, 2013; FDA, 2014a, 2015) “Active Surveillance: Mini-Sentinel monitors the safety of FDA-regulated medical products through assessment of routinely collected electronic healthcare data in response to FDA concerns. It does not require patients or clinicians to initiate reports to FDA.” (FDA, 2014b)

Is Rotavirus A Manufactured Disease?

Many antivaccinationists seem to believe that rotavirus is a disease invented to sell a vaccine. For instance, in a comment to another of his articles: “Posted by: John Stone | April 14, 2015 at 12:26 PM And yet Joel - I never heard of the disease -- nope not even once until suddenly there was a vaccine for it.” Another comment to the same article: “Posted by: Benedetta | May 06, 2015 at 10:57 PM Dr. Harrison; I was born in the mid 1950s. I never heard of it until they made a vaccine for it. And I have a few hours over a masters degree in microbiology. Just saying!” (Stone, 2015d) And, a comment to the article being discussed in this paper: “Posted by: go Rand | August 25, 2015 at 01:56 PM I'm absolutely convinced that Offit was tapped early on to "research" rotavirus (we see his name on a number of rotavirus papers before he invented the vaccine) in order to create the perception of a need for the vaccine. Rotavirus was, as John Stone has pointed out in the past, a practically non-existent disease in the US.” (Stone, 2015a)

According to one recent article:

For centuries, acute diarrhea has been a major worldwide cause of death in young children, and until 1973, no infectious agents could be identified in about 80% of patients admitted to hospital with severe dehydrating diarrhea. . . . Longitudinal surveillance studies following primary infection in young children have shown that rotavirus reinfections are common. However the immune response that develops after primary infection is protective against severe symptoms on reinfection. This observation became the basis for development of live oral rotavirus vaccines. . . Numerous studies over many years

have now confirmed rotavirus as the single most common cause of severe acute dehydrating diarrhea in young children worldwide. (Bishop, 2009)

And, “Despite the magnitude of the problem of infantile diarrhea, the search for the important etiologic agents . . . was unrewarding until the 1970s.” (Estes, 2007, p.1918) By 1978, rotavirus was described as the cause of most childhood gastroenteritis. (Steinhoff, 1978) I went to PubMed, the US Library of Medicine’s online database and typed in “rotavirus” with upper date 12/31/1979 and found a total of 432 articles which, obviously reflects the 1973 discovery of rotavirus. I extended the PubMed search through 12/31/1989 and found a total of 3041 articles.

So, long before the first vaccine for rotavirus, Rotashield, was approved in August 1998, an ever increasing amount of research on rotavirus existed. The discovery of rotavirus in 1973 and ever increasing numbers of published articles predated Dr. Offit’s first research as a newly trained pediatrician by nine years (Offit, 1982ab; 1983). In fact, there were 872 articles on rotavirus in PubMed before Offit began his work in 1982. Offit was still in school when rotavirus was first discovered. And the first rotavirus vaccine, Rotashield, wasn’t Paul Offit’s. Rotateq, the vaccine that Offit and colleagues spent 25 years developing, was approved by the FDA in February 2006.

The fact that Stone never heard of rotavirus, gee, given his total lack of training in epidemiology, infectious diseases, immunology, microbiology, and other related disciplines, doesn’t surprise me; but the arrogance/stupidity to imply that if he hadn’t known something then it probably didn’t exist is incredible; though not surprising given the absolute confidence in their knowledge displayed by many antivaccinationists. And “go Rand” seems to base his being “absolutely convinced” mainly on what John Stone has written. The blind leading the blind? As for whoever Benedetta is, I find it incredibly difficult to believe anyone with graduate training in microbiology would be unaware of the history of microbiology, including the number of diseases that existed prior to discovering the microbes responsible for them. For instance, besides rotavirus:

In 1992, researchers used PCR [Polymerase Chain Reaction] to determine the causative agent of Whipple’s disease, which was previously an unknown bacterium now named *Trophymera whipplei*. Whipple’s disease was first described in 1907 by George Whipple as a gastrointestinal and nervous system disorder caused by an unknown bacillus. No one has been able to culture the bacterium to identify it; thus PCR provides the only reliable methods of diagnosing and treating the diseases. (Tortora, 2016, p.269)

Since in this case it took 85 years to discover the specific bacteria after the disease was first recognized, it is hardly surprising, given the history of microbiology, that severe diarrheal diseases in infants existed for many years prior to the causative agents being discovered.

Did Frank DeStefano and CDC Colleagues Destroy MMR/Autism Data?

According to Stone:

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volving intussusception and death, in a newly published paper concerning the safety of GSK's rotavirus vaccine, Rotarix.

Last month Representative Posey revealed Congress that Thompson told Dr Brian Hooker in a taped telephone conversation regarding the DeStefano MMR paper that:

Sometime soon after the meeting, we decided to exclude reporting any race effects, the co-authors scheduled a meeting to destroy documents related to the study. The remaining four coauthors all met and brought a big garbage can into the meeting room and reviewed and went through all the hard copy documents that we had thought we should discard and put them in a huge garbage can.

According to a paper by Brian S. Hooker, published August 8, 2014 (subsequently retracted October 3, 2014, see below):

This is a reanalysis of the data set, obtained from the U.S. Centers for Disease Control and Protection (CDC), used for the Destefano *et al.* 2004 publication on the timing of the first MMR vaccine and autism diagnoses. (Hooker, 2014a, p.16)

Cohort data were obtained directly as a “restricted access data set” from the Centers for Disease Control and Prevention (CDC) via a Data Use Agreement. Data were deidentified by the CDC in accordance with Family Education Rights and Privacy Act (FERPA) and the Health Insurance Portability and Accountability Act (HIPAA) prior to receipt by the study authors. Use of the CDC specifically for the study described herein was approved by the Simpson University Institutional Review Board, in accordance with U.S. Federal regulations. (Hooker, 2014a, p.17)

And the CDC certainly went out of their way to hide the data when they posted the following on their website:

The data CDC collected for this study continue to be available for analysis by others. CDC welcomes analysis by others that can be submitted for peer-review and publication. For more information on how to access this public-use dataset please go to the this webpage (<http://www.cdc.gov/ncbddd/developmentaldisabilities/maddsp-data-sets.html>) (CDC, 2014)

So, according to Thompson, as parroted by Stone, paper copies of the data from the study were destroyed; yet, the CDC's announcement makes it clear that the data was retained electronically, available for researchers to re-analyze. For many years I went to university and medical libraries photocopying articles. Later I scanned them into PDF files and uploaded them to my PC, sorted into clearly labeled folders. Just to be on the safe side, I also burned a couple of DVD backup copies. So, now I can easily find the articles and e-mail them as attachments to colleagues, while uncluttering my office/home. If the data were only in hard paper copies, Hooker would have had to arrange photocopies, then find a way to upload the raw data to a computer in order to carry out the statistical analyses. Since the data was available in electronic form, he could obtain it in a form directly available for analysis. That means that throwing hard copy documents into a garbage can would do nothing to hide any po-

tential links. This reality - data electronically available and hence indestructible by means of a garbage can - somehow, has been twisted into some nefarious plot to hide data by Stone and other antivaccinationists. And one can wonder about Representative Posey's position as well.

During the Senator McCarthy witch hunt hearings, Joseph Welch, the civilian attorney for the US Army, after McCarthy had once again impugned the character by innuendo of another innocent figure, said: "Mr. Senator, have you no shame. Alas, have you no shame." I would like to think, if Welch were alive today, he would say the same about Stone and other antivaccinationists.

Did the 2004 DeStefano Study Find and Subsequently Hide Any Race Effects?

According to William W. Thompson:

I regret that my coauthors and I omitted statistically significant information in our 2004 article published in the journal Pediatrics. The omitted data suggested that African American males who received the MMR vaccine before age 36 months were at increased risk for autism. Decisions were made regarding which findings to report after the data were collected, and I believe that the final study protocol was not followed.

My concern has been the decision to omit relevant findings in a particular study for a particular sub group for a particular vaccine. (Thompson, 2014)

The CDC responded with the following:

CDC's study about age at first Measles-Mumps-Rubella (MMR) vaccination and autism, published in Pediatrics in 2004, included boys and girls from different ethnic groups, including black children. The manuscript presented the results on two sets of children:

1. All children who were initially recruited for the study, and
2. the subset of children who had a Georgia birth certificate.

Access to the information on the birth certificates allowed researchers to assess more complete information on race as well as other important characteristics, including possible risk factors for autism such as the child's birth weight, mother's age, and education. This information was not available for the children without birth certificates; hence CDC study did not present data by race on black, white, or other race children from the whole study sample. It presented the results on black and white/other race children from the group with birth certificates.

The study looked at different age groups: children vaccinated by 18 months, 24 months, and 36 months. The findings revealed that vaccination between 24 and 36 months was slightly more common among children with autism, and that association was strongest among children 3-5 years of age. The authors reported this finding was most likely a re-

sult of immunization requirements for preschool special education program attendance in children with autism.

The data CDC collected for this study continue to be available for analysis by others. CDC welcomes analysis by others that can be submitted for peer-review and publication. For more information on how to access this public-use dataset please go to the this webpage (<http://www.cdc.gov/ncbddd/developmentaldisabilities/maddsp-data-sets.html>) (CDC, 2014)

The Hooker study states: “When accounting for cases in the cohort that excluded low birth weight (<2500 g) African American children, it was necessary to report results at 31 months rather than 36 months in order to avoid reporting data from age categories or “ cells” that possessed less than 5 individuals.” (Hooker, 2014, p.18)

The DeStefano study actually did include analyses of Race and Birth weight. See TABLE 5 “Characteristics” “Race” “Black” where a total of 137 cases were included and the analysis was done for <18 Months, <24 Months and <36 Months for age of first vaccination. (DeStefano, 2004, p.263)

Neither Thompson nor many anti-vaccinationists seem to understand the basics of statistics. Regardless of how well done an epidemiological study is, it is impossible to ensure that each group is the same on all possible variables that might affect the results except for the variable(s) of interest. Imagine a well-done randomized clinical trial testing some medication for treatment of a specific disease. Patients are randomly assigned to the new treatment or the control group, probably getting the standard treatment. While it would be easy to check if the two groups had the same gender percentages, similar age distributions, and other easily observed variables, it would be almost impossible to ensure they would be equal on every relevant variable, e.g. subclinical comorbidities, genetics, etc. Probability distributions have been developed to determine if one were to randomly assign patients to two groups how often the results would reflect the probability of the randomization process not having been successful, that is, an unequal distribution of variables that might affect the result(s). Statistical significance, for instance at the 0.05 level, means that one would expect to get a result five percent of the time where an unequal distribution of one or more variables could have determined the result as opposed to the treatment. Statistical significance is simply a decision cut-off point. As the study sample gets larger the risk of variables other than the actual treatment being looked at being responsible for the results gets smaller. This is one of the key reasons that replication of studies is important. The probability that replicated studies will result in the same unequal distribution of other variables between groups is quite low. Replications don’t have to be exact.

There is also a 5 percent risk found when doing multiple analyses of the same data, especially post-hoc subgroup analyses. In other words, if one does 20 analyses, it can be assumed that one of the outcomes could be the result of chance, not the hypothesized variable(s). Hooker did his analysis with only five in one cell and was only able to obtain this small number by changing the age range. Years ago I found statistical significance using chi-square with one cell containing only five subjects. I then changed it to four, moving the one subject to another cell, and statistical significance disappeared. Most rational people would NOT base a decision on one subject. Or quite simply, as David Gorski states: “There’s an old saying in epidemiology (and in science in general) that says that if you torture data enough, eventually they will confess.” (Gorski, 2014) For more on statistics, see “**Some Basic Statistics**” on

page 6 of my previous article for ECBT, , “Examples of Deficient Science, Hypocrisy, and Bogus Arguments: A Review of Two Articles by *Age of Autism*’s Anne Dachel (September 30, 2015, Available at: http://www.ecbt.org/images/articles/Examples_of_Deficient_Science_Hypocrisy_and_Bogus_Arguments_-_A_Review_of_Two_Articles_by_Age_of_Autisms_Anne_Dachel.pdf)

Gorski then goes on:

Hooker analyzed a dataset designed from its inception and collection to be analyzed by a case control method using a cohort design.

Requiring the birth certificate was not an “arbitrary” criterion either. It allowed investigators to account for known confounders related to autism risk, such as birth weight, at least in this subset of the case and control groups. I also can’t help but think there is likely to be a confounder that is unaccounted for in this study, particularly given how their increase in risk is found in only one group. In fact, as Reuben at The Poxes Blog (<https://thepoxesblog.wordpress.com/2014/08/22/andrew-jeremy-wakefield-plays-video-director-while-african-american-babies-die-or-something/>) explains, there almost certainly was just such a confounder:

Next come the statistics. Hooker uses Pearson’s chi squared test to see if there is a significant association between MMR and autism in children at different ages. DeStefano et al used conditional logistic regression. For the non-biostatisticians out there, the technique that DeStefano et al used accounts for confounders and effect modifiers, different traits in their population that could skew the results. Hooker’s technique doesn’t really do that, unless you stratify results and use very, very large datasets. Hooker’s approach is more “conservative,” meaning that it will detect small effects and amplify them, and those effects can come from anything.

In other words, Hooker used a method prone to false positives. Then:

The nail in the coffin for the Hooker paper is that autism is usually diagnosed by the time a child is three years old. There was no increased risk at 18 months, higher but not by a whole lot at 24, and then the three-fold increase at 36 months. Gee, was it the MMR vaccine, mister? No, the effect is being modified by age. It’s as if I asked you if your shoe size was bigger at 36 months because you drank milk vs. because you were 36 months. It’s age. It’s the way that autism is diagnosed. You’re going to have more children diagnosed as autistic at 36 months than you will at 18 months or at 24 months. Using the chi square test doesn’t tease this out, Dr. Hooker! That’s more than likely why DeStefano et al used conditional logistic regression, to take age into account in the analysis.

So why did we not see this in the other ethnic groups or in girls? The answer here is simple, again. Hooker had a limited dataset to work with when he boiled it down to African-American baby boys. In this table, for example, he tells us that he had to modify the analysis to 31 months instead of 36 because he had less than 5 children in that group. It's the same goddamned mistake that Andrew Jeremy Wakefield wanted to pass off as legitimate science. ***You cannot, and must not use small numbers to make big assertions...*** [my emphasis] (Gorski, 2014; Reuben, 2014)

Note that Hooker states: "Pearson's chi-squared is, in general, a more conservative analysis and therefore chosen for the present study." This, as clearly discussed above, is totally wrong. By not taking into account possible confounding variables, the test is more prone to false positives. Hooker goes on to claim: "However, our results were also confirmed using a conditional logistic regression design similar to the Destefano *et al.* (CDC) study." (Hooker, 2014, pp.17-18) If this were the case, why not base his paper on the same statistics used by DeStefano or, at least, include both analyses? For additional critiques of Hooker's paper as well as Thompson's claims, see Left Brain Right Brain's "Autism, Atlanta, MMR: serious questions and also how Brian Hooker and Andrew Wakefield are causing damage to the autism communities" (2014a) and "Andrew Wakefield and Brain Hooker complain. Not honestly, but they complain" (2014b).

I could have given extensive references to epidemiological and statistical textbooks; but, as the explanations given by Gorski and Reuben are on the mark and easily accessed, I chose to use them. In any case, it is not surprising, given both Hooker's conflict of interest and poor statistics, that his paper was retracted (see below):

Retraction

The Editor and Publisher regretfully retract the article as there were undeclared competing interests on the part of the author which compromised the peer review process. Furthermore, post-publication peer review raised concerns about the validity of the methods and statistical analysis, therefore the Editors no longer have confidence in the soundness of the findings. We apologise to all affected parties for the inconvenience caused. (Hooker, 2014b)

Summary

1. Stone claims that a recent article by Haber *et al.* (2015) omitted a large number of cases of intussusception and some deaths. Stone writes: "a careful review of the database reveals no less than 565 cases for the period. The paper claims to have excluded only 4 reports as unconfirmed (making a total of only 112)." Stone's article attacks the integrity of CDC researchers.
2. Stone repeats the claims made by Thompson, the so-called CDC whistleblower, that the CDC destroyed data from an earlier study (DeStefano, 2004) and withheld a finding associating MMR vaccine and African American males under 36 months of age.
3. Stone subsequently admitted he was wrong about Haber *et al.* omitting cases of intussusception; but, in a lame attempt to justify himself, he writes: "that I had overlooked the fact that the paper selects US cases only - that there are only a trickle of cases from the US against a relative flood

from abroad - and this is basis of massive selection bias, particularly in relation to deaths. It also shows that the US reporting system while always vastly inadequate is wilting. Pharmaceutical companies are required by law to forward reports from abroad where they come to their attention. . . anyone interested in the safety of the vaccine to US children or any other would have considered all of the reports. (Stone, 2015c)

4. Stone failed to note that the Haber *et al.* study included verifying the reported cases from the medical records, something that would be near impossible for foreign cases. Stone also fails to understand that deaths reflect levels of medical care which can be less effective than in the US. He also fails to understand that diagnoses vary in accuracy, the reason for Haber *et al.* conducting chart audits. Stone also fails to understand that the denominator, that is, the population of the US vs. the non-US population influences the incidence of cases. Quite simply, the larger number of cases from outside the US could reflect a much larger population and, thus, not a higher incidence of cases.
5. By analogy, using US crime data, most Americans would be interested in how safe it is in the US, NOT how many Americans are killed abroad.
6. Stone claims, without any justification, that pharmaceutical companies would proportionately receive more reports abroad of vaccine-related adverse events and would be more law abiding in reporting them than in the US.
7. While Stone states: “anyone interested in the safety of the vaccine to US children or any other would have considered all of the reports;” he and other antivaccinationists, when critiquing the effectiveness of vaccines, exclude international data on vaccine-preventable disease morbidity and mortality. In other words, if international data supports their position, great, if it doesn’t, ignore it.
8. Stone and other antivaccinationists imply that since they had not heard of rotavirus prior to the introduction of the rotavirus vaccine that it is a disease manufactured to sell a vaccine. Rotavirus was first discovered in 1973, and was quickly recognized to be the major cause of childhood diarrhea, long before development of a vaccine had been contemplated. Stone apparently is unaware that approximately 80% of serious cases of diarrhea in infants resulting in hospitalization had unknown causes prior to the 1970s when rotavirus was discovered and long before the first vaccine was approved the medical literature contained an ever-increasing number of studies of rotavirus. Fascinating how Stone twists his ignorance into a justification for attacking the vaccine.
9. Despite Thompson’s repeated claims that the CDC destroyed data, parroted by Stone and other antivaccinationists, the data is not only available in electronic form for re-analysis as posted on the CDC website; but Brian Hooker actually obtained the data and used them for his now-retracted article.
10. Despite Thompson’s repeated claims that the DeStefano article omitted analyses on African American boys, they did include this in their paper. However, the article by Hooker was retracted because he used an analysis of a cohort design for data collected for a case-control study and based his conclusion on changing the age range so he could get a minimum of 5 kids in one cell of the analysis. Stone and other antivaccinationists not only ignore this; but fail to understand some of the basics of epidemiological design and statistical significance testing.

Discussion and Conclusion

So, the numbers given in the Haber *et al.* article are accurate, justifiable, and the study did NOT lose 80% of cases and 18 deaths. The data from the DeStefano study were not destroyed; but not only retained in electronic format but made available for re-analyses. Since Hooker actually obtained the data,

why do Stone and other antivaccinationists continue to lodge such unjustified attacks on DeStefano and the CDC? Perhaps, their absolute certainty that they are right, in their minds, has resulted in an ends justifies the means approach, in this case, the lie said often enough becomes the truth. Or, perhaps, they are just too stupid to understand that getting rid of cluttering hard copies does not constitute destruction of data when the data are retained electronically and made available for re-analysis. And Stone and other antivaccinationists also continue with claims that the DeStefano article omitted findings of an association between the MMR vaccine and African American boys, ignoring that the article actually did include such an analysis; but did not include post-hoc subgroups analyses based on changing the age range to get a minimum of 5 in one cell and using the wrong statistic, that is taking data obtained for a case-control study and analyzing it as a cohort study.

Having read numerous articles by Stone, I see no evidence that he possesses any basic knowledge of epidemiology, biostatistics, immunology, microbiology, or the history and current status of infectious diseases, that is, many are only a plane flight away from the US. Instead, he looks for articles that find fault with vaccines and bases his *Age of Autism* articles on them without having the minimal skills to evaluate their validity. In addition, when he has based one of his articles on a newspaper article, preliminary study, or even journal article, if subsequent research finds the initial claim wrong, Stone has never as far as I've seen admitted this. Sometimes he finds minor typos or errors and implies that they invalidate the main findings, something NO legitimate scientist would do. No study, no paper is perfect. What's more, when he can't find fault directly with some research, he resorts to *ad hominem* attacks. That is, if he can't find fault, then the researchers must have falsified the data or, at the least, had a conflict of interest. For more on the logical fallacy of *ad hominem* attacks, see the section of a previous ECBT article by me, "Logical Fallacies and More Hypocrisy: The Ad Hominem Attack" (Harrison, 2015, pp.12-14). How does he know? Because the findings did not jibe with his rigid ideology. In other words, Stone is the litmus test for what is true and what is false. And Stone seldom if ever admits he is wrong, at least not without some twisted attempt to extricate himself.

While working on this paper, a recent article by Anne Dachel, also on *Age of Autism*'s website, continues the lie as clearly indicated by the article's title: "Reality Check: CDC Scientist Admits Data of Vaccines and Autism Was Trashed by Anne Dachel" (*Age of Autism*, November 2, 2015). Available at: <http://www.ageofautism.com/2015/11/reality-check-cdc-scientist-admits-data-of-vaccines-and-autism-was-trashed.html> And a Google search of the internet results in 100s of such claims.

I may at a later date write more about the rotavirus and intussusception; but there are so many topics and each of my articles takes a lot of time to research, write, and send out for feedback/critiques, that I can only do so much. However, anyone who takes the time to carefully read my articles on *Every Child By Two*, including checking out the references, that is, anyone with an open mind should, at the least, begin to question the credibility of antivaccinationists, not only their poor scholarship, deficient understanding of science, often lack of common sense; but their character in resorting to *ad hominem attacks*, refusal to admit when they are wrong, and hypocrisy.

If this were simply a debate on Piltdown Man, it would be partly sad because of the fraud involved and, perhaps, intellectually amusing. However, antivaccinationists are undermining one of the most important tools we have to prevent suffering, morbidity and mortality, one of the main contributors to increases in life-expectancy. Parents, in deciding on whether to vaccinate their children or not, should

be wary of claims made by people so deficient in just about everything. Do NOT allow the lie told most often to become the truth!

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References:

Armstrong, GL, Conn, LA, Pinner, RW.(1999 Jan 6). Trends in Infectious Disease Mortality in the United States During the 20th Century. *JAMA*; 281(1): 61-66.

Baker, MA, Nguyen, M, Cole, DV *et al.* (2013 Dec). Post-licensure rapid immunization safety monitoring program(PRISM) data characterization. *Vaccine*; 31(Suppl 10): K98-112.

Bishop, Ruth (2009) Discovery of Rotavirus: Implications for Child Health. *Journal of Gastroenterology and Hepatology*; 24 Suppl.3: S81–S85

CDC (1999 Jul 30). Achievements in Public Health, 1900-1999: Control of Infectious Diseases. *Morbidity and Mortality Weekly Report*; 48(29); 621-647. Available at: <http://www.cdc.gov/mmwr/PDF/wk/mm4829.pdf>

CDC (last update 2014 Apr 1). Vaccines and Immunizations: Chapter 21: Surveillance for Adverse Events Following Immunization Using the Vaccine Adverse Event Reporting System (VAERS)Chapter 21: Surveillance for Adverse Events Following Immunization Using the Vaccine Adverse Event Reporting System (VAERS). Available at: <http://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html>

CDC (2014 Aug 25). CDC Statement Regarding 2004 Pediatrics Article, "Age at First Measles-Mumps-Rubella Vaccination in Children With Autism and School-matched Control Subjects: A Population-Based Study in Metropolitan Atlanta". Available at: <http://www.cdc.gov/vaccinesafety/Concerns/Autism/cdc2004pediatrics.html>

CDC (2015a). Appendix E: Reported Cases and Deaths from Vaccine Preventable Diseases, United States, 1950-2013. *Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book, 13th Edition*. Available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/E/reported-cases.pdf>

CDC (2015b). Appendix E: Impact of Vaccines in the 20th & 21st Centuries. *Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book, 13th Edition*. Available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/E/impact.pdf>

CDC (2015c). Chapter 4: Vaccine Safety. Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book, 13th Edition. Available at:
<http://www.cdc.gov/vaccines/pubs/pinkbook/safety.html>

CDC (2015d). Vaccine Safety Publications. Available at:
<http://www.cdc.gov/vaccinesafety/research/publications/index.html>

Clark HF, Offit, PA, Parashar, UD. Chapter 30: Rotavirus vaccines. In Plotkin SA, Orenstein WA, Offit PA (Eds.) Vaccine. 6th ed. Elsevier Saunders: 669-687.

Cunningham, RM, Boom, JA, Baker, CJ. (2010). Vaccine-Preventable Disease: The Forgotten Story, Updated Edition. Texas Children's Hospital. Available at:
<http://web.texaschildrens.org/multimedia/flipbook/vaccine-book/>

DeStefano, F, Bhasin, TK, Whompsen, WW *et al.* (2004 Feb). Age at First Measles-Mumps-Rubella Vaccination in Children With Autism and School-Matched Control Subjects: A Population-Based Study in Metropolitan Atlanta. Pediatrics; 113(2): 259-266.

Estes, MK, Kapikian, AZ (2007). Volume Two: Chapter 53: Rotavirus. In Knipe, DM *et al.* Fields Virology Fifth Edition. Lippincott Williams & Wilkins: 1917-1974.

FDA (2014a). Mini-Sentinel: Welcome to Mini-Sentinel. Available at: <http://www.mini-sentinel.org/default.aspx>

FDA (accessed 2015). Mini-Sentinel - FDA's New Tool for Monitoring the Safety of FDA-Approved Products. Available at:
<http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM301401.pdf>

FDA (2014c). Mini-Sentinel: Background. Available at: http://www.mini-sentinel.org/about_us/default.aspx

Gorski, David (2014 Aug 25). Did a high ranking whistleblower really reveal that the CDC covered up proof that vaccine cause autism in African-American boys? Science-Based Medicine. Available at:
<https://www.sciencebasedmedicine.org/did-a-high-ranking-whistleblower-really-reveal-that-the-cdc-covered-up-proof-that-vaccines-cause-autism-in-african-american-boys/>

Haber P, Parashar UD, Haber M, DeStefano F (2015). Intussusception After Monovalent Rotavirus Vaccine—United States, Vaccine Adverse event Reporting System (VAERS), 2008-2014; 33(38): 4873-4877.

Harrison, Joel A. (2015 Sep 30). Examples of Deficient Science, Hypocrisy, and Bogus Arguments: A Review of Two Articles by *Age of Autism's* Anne Dachel; Every Child By Two. Available at:
http://www.ecbt.org/images/articles/Examples_of_Deficient_Science_Hypocrisy_and_Bogus_Arguments_-_A_Review_of_Two_Articles_by_Age_of_Autisms_Anne_Dachel.pdf

Hooker, Brian S. (2014a Aug 8). Measles-mumps-rubella vaccination timing and autism among young african american boys: a reanalysis of CDC data. *Translational Neurodegeneration*; 3: 16-21. Available at: <http://www.translationalneurodegeneration.com/content/pdf/2047-9158-3-16.pdf>

Hooker, Brian S. (2014b). Retraction: Measles-mumps-rubella vaccination timing and autism among young african american boys: a reanalysis of CDC data. *Translational Neurodegeneration*; 3: 22. Available at: <http://www.translationalneurodegeneration.com/content/3/1/22>

LaRussa, PS, Edwards, KM, Dekker, CL *et al.* (2011 May). Understanding the Role of Human Variation in Vaccine Adverse Events: The Clinical Immunization Safety Assessment Network. *Pediatrics*; 127(Suppl.1): S65-S73. Available at: http://pediatrics.aappublications.org/content/pediatrics/127/Supplement_1/S65.full.pdf

Left Brain Right Brain (2014a Aug 26). Autism, Atlanta, MMR/ serious questions and also how Brian Hooker and Andrew Wakefield are causing damage to the autism communities. Available at: <http://leftbrainrightbrain.co.uk/2014/08/26/autism-atlanta-mmr-serious-questions-and-also-how-brian-hooker-and-andrew-wakefield-are-causing-damage-to-the-autism-communties/>

Left Brain Right Brain (2014b Oct 23). Andrew Wakefield and Brian Hooker complain. Not honestly, but they complain. Available at: <http://leftbrainrightbrain.co.uk/2014/10/23/andrew-wakefield-and-brian-hooker-complain-not-honestly-but-they-complain/>

National Vaccine Information Center. Found 565 cases where Vaccine is RV1 and Symptom is Intussusception and Appearance Date from '2008-02-01' to '2014-12-31'. (Accessed August 25, 2015) Available at: <http://www.medalerts.org/vaersdb/index.php>

Offit, P.A. (1982a) Principal Investigator of Grants: The study of rotaviruses with monoclonal antibodies, Individual National Research Service Award, F32 AI 06733, *The National Institutes of Health*, 1982-1984, \$36,000.

Offit, P.A., and D. Rubin (1982b Aug). Viral diseases: infections of the gastrointestinal tract. *Comprehensive Therapy*; 8(2): 21-26.

Offit, P.A., H.F. Clark, W.G. Stroop, E.M. Twist, and S.A. Plotkin (1983 Jul). The cultivation of human rotavirus, strain 'WA', to high titer in cell culture and characterization of the viral structural polypeptides. *Journal of Virological Methods*; 7(1): 29-40.

Offit, PA, DeStefano, F (2013). Chapter 76: Vaccine Safety in Plotkin, SA, Orenstein, WA, Offit, PA (Eds). *Vaccine*, 6th Edition. Elsevier: 1464:1480.

Reuben (2014 Aug 22). Andrew Jeremy Wakefield plays video director while African-American Babies die, or something. *The Poxes Blog*. Available at: <https://thepoxesblog.wordpress.com/2014/08/22/andrew-jeremy-wakefield-plays-video-director-while-african-american-babies-die-or-something/>

Riley, James C. (2001). *Rising Life Expectancy: A Global History*. Cambridge University Press.

Roush, SW, Murphy, TV *et al.* (2007 Nov 14). Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States. *JAMA*; 298(18): 2155-2162. Available at: <http://jama.jamanetwork.com/article.aspx?articleid=209448>

Steinhoff, MC (1978). Viruses and Diarrhea: A Review. *American Journal of Diseases in Children*; 132:302-307.

Stone, John (2015a Aug 25). DeStefano Rides Again: GSK Rotavirus Vaccine Study Loses 80% Of Cases And 18 Deaths, *Age of Autism*. Available at: <http://www.ageofautism.com/2015/08/destefano-rides-again-gsk-rotavirus-vaccine-study-loses-80-of-cases-and-18-deaths.html>

Stone, John (2015b Oct 27). DeStefano Rides Again: GSK Rotavirus Vaccine Study Loses 80% Of Cases And 18 Deaths, *Age of Autism*. Available at: <http://www.ageofautism.com/2015/10/destefano-rides-again-gsk-rotavirus-vaccine-study-loses-80-of-cases-and-18-deaths.html>

Stone, John (2015c Oct 28). Addendum: DeStefano Rides Again: GSK Rotavirus Vaccine Study Loses 80% Of Cases And 18 Deaths, *Age of Autism*. Available at: <http://www.ageofautism.com/2015/10/destefano-rides-again-gsk-rotavirus-vaccine-study-loses-80-of-cases-and-18-deaths.html>

Stone, John (2015d Apr 7). Offit Vaccine Under Review In France After Baby Deaths. *Age of Autism*. Available at: <http://www.ageofautism.com/2015/04/offit-vaccine-under-review-in-france-after-baby-deaths.html>

Strebel PM *et al.* (2013). Chapter 20: Measles Vaccine. In Plotkin SA, Orenstein WA, Offit PA (Eds.) *Vaccine*. 6th ed. Elsevier Saunders: 352-387.

van Panhuis, WG, Grefenstette, J, Jung, SY *et al.* (2013 Nov 28). Contagious Diseases in the United States from 1888 to the Present. *NEJM*; 369(22): 2152-2158.

Thompson, William W. (2014 Aug 27). Press Release, “Statement of William W. Thompson, Ph.D., Regarding the 2004 Article Examining the Possibility of a Relationship Between MMR Vaccine and Autism.” Available at: <http://www.morganverkamp.com/august-27-2014-press-release-statement-of-william-w-thompson-ph-d-regarding-the-2004-article-examining-the-possibility-of-a-relationship-between-mmr-vaccine-and-autism/> (Accessed November 1, 2015)

Tortora, Gerald J, Funke, Berdell R, Case, Christine L. (2016). *Microbiology: An Introduction*, Twelfth Edition. Pearson.

VAERS (accessed 2015 Nov 10). About the VAERS program. Available at: <https://vaers.hhs.gov/about/index>

Whitney, CG, Zhou, F, Singleton, J, Schuchat, A (2014 Apr 25). Benefits from Immunization During the Vaccines for Children Program Era — United States, 1994-2013. *Morbidity and Mortality Weekly Report*; 63(16): 352-355. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm>

WHO (2015 Feb). Measles Fact Sheet No. 286. Available at:
<http://www.who.int/mediacentre/factsheets/fs286/en/>

WHO (Accessed 2015 Oct 29). Estimated rotavirus deaths for children under 5 years of age: 2008, 453 000. Available at:
http://www.who.int/immunization/monitoring_surveillance/burden/estimates/rotavirus/en/

Zhou, F, Shefer, A, Wenger, J *et al.* (2014 Apr). Economic Evaluation of the Routine Childhood Immunization Program in the United States, 2009. *Pediatrics*; 133(4): 577-85. Available at:
<http://pediatrics.aappublications.org/content/133/4/577.long>